K092019

SEP 15 2009

510k Premarket Notification Summary

Submitted by:

Sun Nuclear Corporation
425-A Pineda Court
Melbourne, FL 32940
Ph: 321-259-6862
Fax: 321-259-7979

Classification Name: Unknown

Common Name: Electrometer

Proprietary Name: PC Electrometer – Model 1014

Establishment Registration Number: 1038814

Classification: Class II, Classification 90LYE

Performance Standards: To our knowledge, none have been established

Substantial Equivalence: This instrument is similar in function to Sun Nuclear Model 1010 Dosimetry Electrometer #K002444

Description and Use:

The PC Electrometer Model 1014 has two triaxial BNC inputs for connection to ion chambers for dosimetric measurements. The ion chamber voltage bias can be adjusted to various levels at either polarity. For air density correction, there are internal temperature and pressure sensors that measure ambient conditions and an input for an external remote temperature sensor. A USB port provides power and data communication with a Personal Computer (PC) which runs the application software to display and record data; an auxiliary power jack is also provided in case USB power is not available. The conductive enclosure (4cm x 10.5cm x 14cm) provides EMI shielding and LED status indicators. The PC Electrometer Model 1014 is a Radiation Oncology Medical Physics tool used to measure ion current from either ion chambers or diode dosimeter. These applications include periodic or annual calibration of the radiation output of the delivery machine when a calibrated ion chamber is connected such as AAPM Report 67 (TG-51) as well as periodic QA applications that do not require calibrated radiation detectors, such as described in AAPM Report 13 (TG-22, 24), AAPM Report 46 (TG-40) TG-40 and soon to be published TG-142, an update to TG-40.

Intended Use:

The PC Electrometer Model 1014 is a dosimetry electrometer intended for measuring the output charge of an ion chamber in a radiotherapy beam and using these measurements in dosimetry protocols, such as Report 67 as recommended by the AAPM Task Group #51. . In addition the PC Electrometer Model 1014 is intended for measurements with ion chamber or diode detectors as recommended during periodic QA testing protocols such as Report 46, Comprehensive QA for Radiation Oncology, as recommended by the AAPM Task Group #40. as well as AAPM Report 13 (TG-22, 24 and soon to be published TG-142, an update to TG-40.

Similarities and Differences between SNC Model 1010 and SNC Model 1014:

Similarities:

1. Both designed and manufactured by Sun Nuclear.
2. Both have similar Intended Uses
3. Both use high impedance operational amplifiers with capacitors to measure charge
4. Both measure bi-polar charge (current) from ion chambers and diode radiation detectors
5. Both have ion chamber voltage bias that can be adjusted to various levels at either polarity.

Differences:

1. 1014 has 2 detector inputs, 1010 has one
2. 1014 has (internal and external) temperature sensors and an internal pressure sensor, 1010 has none unless it was connected to the SNC Data Bridge.
3. 1014 has data logging ability to the PC; the 1010 required a SNC Data Bridge for data logging.
4. 1014 power comes from USB connection, 1010 uses internal batteries for power.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 15 2009

Ms. Noel Downey
Project Manager
Sun Nuclear Corporation
425-A Pineda Court
MELBOURNE FL 32940

Re: K092019
Trade/Device Name: 1014 – PC Electrometer
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 24, 2009
Received: July 6, 2009

Dear Ms. Downey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K092019

Device Name: 1014 – PC Electrometer

Indications for Use:

The PC Electrometer Model 1014 is a dosimetry electrometer intended for measuring the output charge of an ion chamber in a radiotherapy beam and using these measurements in dosimetry protocols, such as Report 67 as recommended by the AAPM Task Group #51. . In addition the PC Electrometer Model 1014 is intended for measurements with ion chamber or diode detectors as recommended during periodic QA testing protocols such as Report 46, Comprehensive QA for Radiation Oncology, as recommended by the AAPM Task Group #40. as well as AAPM Report 13 (TG-22, 24 and soon to be published TG-142, an update to TG-40.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092019